510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k122370

B. Purpose for Submission:

This submission is for the addition of wireless transmission capabilities with the Medtronic MiniMed 530G Insulin pump, a component of the Medtronic MiniMed 530G System.

C. Measurand:

Glucose in fresh capillary whole blood from the finger and palm.

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

Bayer HealthCare LLC, Diabetes Care

F. Proprietary and Established Names:

Contour NEXT LINK Wireless Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 Glucose Test System

2. Classification:

   Class II

3. Product code:

   NBW - Blood glucose test system, over the counter

   LFR, Glycose Dehydrogenase, Glucose

4. Panel:

   (75) Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:
   The Contour NEXT LINK Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The Contour NEXT LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The system consists of a Contour NEXT LINK Wireless Blood Glucose Meter and Contour NEXT Test Strips.

   Contour NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.

   The Contour NEXT LINK Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin Pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed Paradigm REAL-TIME Insulin Pumps or Medtronic MiniMed 530G Insulin Pumps or Guardian REAL-TIME Monitor and facilitate transfer of information to Medtronic MiniMed Carelink Therapy Management Software through use of radio frequency communication.

   The Contour NEXT LINK Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

3. Special conditions for use statement(s):

   For over-the-counter use and for prescription use

   For single-patient use only

   For use with fresh capillary whole blood samples drawn from the fingertip and palm only

   Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

May be used to transmit glucose values to compatible Medtronic MiniMed devices and facilitate transfer of information to Medtronic MiniMed Carelink® Therapy Management Software through use of radio frequency communication.

Not for use on critically ill patients (e.g. those with severe hypotension or shock, hyperglycemic-hyperosmolar state, hypoxia, severe dehydration, diabetic ketoacidosis).

4. Special instrument requirements:

   Contour NEXT LINK Wireless Blood Glucose Meter

I. Device Description:

The Contour NEXT LINK Wireless Blood Glucose Monitoring System consists of a meter that is the same as the Contour NEXT Link Wireless Blood Glucose Monitoring System (k110894), dry reagent strips and liquid controls to be used for the measurement of glucose in capillary whole blood by persons with diabetes. The system is automatically coded as is the predicate device. Blood glucose results are displayed on the meter display and stored in the meter's memory. The system also contains radio frequency (RF) functions for the transmitting of BGM results to compatible Medtronic Minimed insulin pumps. The RF function can also serve as a pass through for data being transmitted from Medtronic Minimed insulin pumps to Medtronic's Minimed PC based data management software.

The Contour NEXT LINK Wireless Blood Glucose Monitoring System consists of the following components:

- ContouR NEXT LINK blood glucose meter
- Contour NEXT blood glucose test strips
- Contour NEXT control solution – Level 1
- Contour NEXT control solution – Level 2

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Contour NEXT LINK Wireless Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

   k110894

3. Comparison with predicate:

Characteristic	Contour NEXT Link Wireless (Candidate Device)	Contour NEXT Link Wireless (Predicate Device k110894)

Indications for Use	The Contour NEXT LINK Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The Contour NEXT LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Contour NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The Contour NEXT LINK Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.	Same
Wireless Communication	The Contour NEXT LINK Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin Pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed Paradigm REAL-TIME Insulin Pumps or **Medtronic MiniMed 530G Insulin Pumps** or Guardian REAL-TIME Monitor and facilitate transfer of information to Medtronic MiniMed Carelink Therapy Management Software through use of radio frequency communication.	The CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed Paradigm® REAL-TIME Insulin Pumps or Guardian REAL-TIME Monitor and facilitate transfer of information to Medtronic MiniMed Carelink Therapy Management Software through use of radio frequency communication.
Test Strip	Contour NEXT Test Strip	Same

Algorithm	Multi-pulse algorithm	Same
User interface	Alphanumeric, Iconic, Native Language	Same
Number of buttons	4	Same
Display (technology)	Graphical (OLED)	Same
Radio-frequency communication	Yes	Same

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

The Contour NEXT LINK wireless blood glucose test is based on measurement of electrical current caused by the reaction of glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and potassium ferricyanide. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.

M. Performance Characteristics (if/when applicable):

The meter and test strips are identical to the predicate previously cleared in k110894. Therefore, the performance testing from the predicate submission is applicable to the Contour NEXT LINK Wireless Blood Glucose Monitoring System.

1. Analytical performance:

   a. Precision/Reproducibility:

   Established in k110894.

   b. Linearity/assay reportable range:

   Established in k110894.

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   Established in k110894.

   d. Detection limit:

The measuring range of the Contour NEXT LINK Wireless Blood Glucose Monitoring system is 20-600 mg/dL based on studies established in k110894.

e. *Analytical specificity:*

Established in k110894.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Established in k110894.

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

User Performance Study:

Meter and test strip user performance was established in k110894. The ability of users to interact with transmitted glucose values on the MiniMed 530G system was approved under P120010.
Alternative Site Testing: Established in k110894.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose results were cited from the literature[1] and presented in the labeling as follows:

Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow 70-110 mg/dL in the fasting state. You should consult with your healthcare provider for expected glucose values specific to your needs.

[1] Longo DL, et al.: Harrison's Principles of Internal Medicine-18th edition, 2011:3003.

N. Instrument Name:

Contour NEXT Link Wireless Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

The purpose of this submission is to add the capability to transmit data to the Medtronic MiniMed 530G Insulin Pump. This transmission has been also approved as part of P120010. Transmissions to the Medtronic MiniMed Paradigm Insulin Pumps, Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps, Medtronic MiniMed Paradigm REAL-TIME Insulin Pumps, Guardian REAL-TIME Monitor and the transfer of information to the Medtronic MiniMed Carelink Therapy Management Software were previously cleared in k110894 and various PMA supplements under P980022.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types in k110894.

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

The glucose test is intended to be used with capillary whole blood from the finger and palm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

There is no calibration required for the Contour-Next Link blood glucose meter by the user. The meter is automatically coded.

6. Quality Control:

Established in k110894.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at or lower than the 8th grade level.

2. Customer service is available 24 hours/day, 365 days a year. Toll free phone number is 1-800-348-8100 for Bayer Diabetes Care customer support.

3. Temperature and humidity operating conditions were established in k110894.

4. EMC testing: No additional testing necessary for this device. EMC testing data were reviewed as part of k110894.

5. Infection Control: Infection control was established in k110894.

6. Altitude Study: An altitude study was performed in k110894.

7. Hematocrit study: A hematocrit study was performed in k110894

8. Sample Volume Study: The minimal sample volume was established to be 0.6 μL in k110894.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.